In the United States Court of Federal Claims

No. 13-349V

(Filed Under Seal: August 22, 2023) (Reissued: September 12, 2023)*

FOR PUBLICATION

CRISTAL BELLO,	*
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Petitioner,	*
	*
v.	*
	*
SECRETARY OF HEALTH AND	*
HUMAN SERVICES,	*
	*
Respondent.	*
	*

Mark T. Sadaka, Sadaka Associates LLC, Englewood, NJ, for Petitioner.

Kimberly S. Davey, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C., for Respondent, United States. With her on briefs were Brian M. Boynton, Principal Deputy Assistant Attorney General, C. Salvatore D'Alessio, Director, Heather L. Pearlman, Deputy Director, and Lara A. Englund, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

OPINION AND ORDER

Petitioner Cristal Bello, who experienced premature ovarian failure after receiving the Gardasil vaccine, sought relief under the National Childhood Vaccine Injury Compensation Program. 42 U.S.C. §§ 300aa-10 to 34 ("Vaccine Act"). The Special Master found that Petitioner had not carried her burden to prove causation and denied recovery. See Entitlement Decision (ECF 174). Petitioner filed a motion for review, which has been fully briefed and argued. Although certain errors appear

^{*} This Opinion was issued under seal on August 22, 2023. The parties were directed to propose redactions by September 5, 2023. No proposed redactions were submitted. The Court hereby releases publicly the Opinion and Order of August 22 in full.

¹ Petitioner's Br. in Support of Motion for Review ("Pet. Br.) (ECF 176); Respondent's Br. Opposing Motion for Review ("Resp. Br.") (ECF 178); Tr. (ECF 182).

in the record, the Special Master's ultimate decision was not arbitrary and capricious, so the motion for review is **DENIED**.²

BACKGROUND

I. The Vaccine Act

To obtain compensation under the Vaccine Act, a petitioner must prove that a vaccine caused an injury. Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). There are two ways to show causation: (1) through "a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table ('Table injury')," id. (citing 42 U.S.C. § 300aa-14(a)), or (2) by proof of causation in fact "where the complained-of injury is not listed in the Vaccine Injury Table ('off-Table injury')," id. (citing 42 U.S.C. §§ 300aa-13(a)(1), 300aa-11(c)(1)(C)(ii)(I)). For off-Table injuries, causation in fact has three elements: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Id.

A petitioner always must prove causation of off-Table injuries by preponderance of the evidence. See, e.g., Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1366 (Fed. Cir. 2012); Althen, 418 F.3d at 1278.3 Although the petitioner's burden does not "require identification and proof of specific biological mechanisms," Knudsen v. Sec'y of Health & Hum. Servs., 35 F.3d 543, 549 (Fed. Cir. 1994), "a 'plausible' or 'possible' causal theory" is not enough, see Boatmon v. Sec'y of Health & Hum. Servs., 941 F.3d 1351, 1360 (Fed. Cir. 2019) (quoting Moberly ex rel. Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010)). Proof of causation requires "a reputable medical or scientific explanation that pertains specifically to the petitioner's case." See Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010); Moberly, 592 F.3d at 1322; see also Knudsen, 35 F.3d at 549 ("[C]ausation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular [patient] without detailed medical and scientific exposition on the biological mechanisms."). A theory of causation must be supported by medical records or an expert's opinion. Althen, 418 F.3d at 1279 (citing 42 U.S.C. § 300aa-13(a)(1)).

² This Court has jurisdiction. See 42 U.S.C. §§ 300aa-11(c), 300aa-16(a). Petitioner timely moved for review. See 42 U.S.C. § 300aa-12(e)(1).

³ The government can rebut proof of causation by showing, "also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Althen*, 418 F.3d at 1278 (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994)); see 42 U.S.C § 300aa-13(a)(1)(B).

II. Procedural and Factual History

This is one of several cases alleging that the Gardasil vaccine — which is meant to prevent human papillomavirus infections — causes premature ovarian failure, an off-Table injury. See 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a)(XVI). The cases were consolidated before the Special Master, who held that the petitioners can satisfy Althen prong one when their ovarian failure is "autoimmune in nature." See Ruling on Althen Prong One at 9 (ECF 147). Under that ruling — which is not challenged here — Petitioner must prove that she personally suffers from ovarian failure caused by autoimmunity and that there is a logical and proximate sequence under Althen prongs two and three. See id. at 24.

The Special Master explained in detail how she would evaluate whether a petitioner has established autoimmune ovarian failure:

In cases where there is evidence of lymphocytic oophoritis, adrenal or ovarian autoantibodies, and comorbid autoimmune disorders, I will presume the [ovarian failure] is autoimmune in nature. If all three of these factors are not present, a petitioner may still be able to establish it more-likely-than-not that her [ovarian failure] is autoimmune, given her particular medical history.

Id. at 14; see also Entitlement Decision at 33.

The most relevant facts concerning Petitioner are as follows. On May 25, 2010, when she was 23 years old, Petitioner visited a gynecologist. *See* Pet. Exh. 2 at 65 (ECF 8-3). She reported that her last menstrual period had begun two days earlier. *Id.* Her medical record suggests that the doctor observed a cervical abnormality, but it is not obvious from the notes what was the matter. *Id.* The doctor recommended that Petitioner receive the Gardasil vaccine, *id.*, which was administered on June 4. *Id.* at 64.

Aspects of Petitioner's subsequent medical history are murky. On August 6, Petitioner reported to her doctor that she had been experiencing hot flashes and other symptoms for two weeks. *Id.* at 59. The doctor ordered laboratory tests, which showed post-menopausal (*i.e.*, elevated) levels of certain hormones. *Id.* at 50; *see also* Pet. Exh. 3 at 24 (ECF 8-4). Those hormone levels were within the normal range a month later. Pet. Exh. 2 at 48.

In December 2010, Petitioner faxed a message to a new gynecologist. She reported that she experienced hot flashes "[i]n the beginning of August" and had spoken to her doctor, who ran laboratory tests. See Pet. Exh. 2 at 32. She reported that she "missed [her] menstrual cycle for about 3 months so [the doctor] took [her] off birth control ... and we monitored the levels for the next 2 months." Id. The hot

flashes "went away," but had come back, and she was "again ... two weeks late on [her] cycle." *Id.* at 32–33. Tests in December showed elevated hormone levels again. Pet. Exh. 2 at 41–42.

The dates of Petitioner's periods after May are not clear from the record. At a doctor's appointment in December, after her fax message, she reported that her last period began in October 2010. See Pet. Exh. 3 at 12. In 2014, she reported a period in August 2010, Pet. Exh. 12 at 2 (ECF 52-2), though the parties agree that was likely error. Tr. at 10–13, 59. In February 2011 she reported a menstrual period as late as November 2010. See Pet. Exh. 3 at 10. But ultimately she was diagnosed with premature ovarian failure. See Entitlement Decision at 33 ("The parties do not dispute that Petitioner suffers from [premature ovarian failure].").

As mentioned, the Special Master's *Althen* prong one ruling identified several conditions that, when appearing together, would lead her to presume that a petitioner's ovarian failure was autoimmune in nature. Ruling on *Althen* Prong One at 9. Petitioner was never diagnosed with two of those conditions. Petitioner never had a positive test result for adrenal or anti-ovarian antibodies. *See* Entitlement Decision at 33–34; Pet. Exh. 5 at 23–29, 33–36, 47, 51 (ECF 8-6); Pet. Exh. 121 at 3 (ECF 156). She also showed no signs for oophoritis. *See* Entitlement Decision at 34; Pet. Exh. 3 at 11–13; Gov. Exh. N at 4 (ECF 173-1); Pet. Exh. 121 at 3.

Instead, Petitioner had positive test results for antinuclear antibodies in 2011 and 2017, although she also had negative results in 2010 and 2012. See Entitlement Decision at 34–35, 9–10, 12; Pet. Exh. 9 at 72 (ECF 23-2); Pet. Exh. 24 at 38 (ECF 90-1); Pet. Exh. 137 at 8 (ECF 166-1); Pet. Exh. 141 at 2 (ECF 171-4); Pet. Exh. 143 at 3, 9–11 (ECF 171-6). She also may have received a diagnosis of psoriasis. See Entitlement Decision at 36; Pet. Exh. 123 at 6–9, 10–13 (ECF 163-1); Pet. Exh. 126 (ECF 165-1); Pet. Exh. 127 (ECF 165-2); Gov. Exh. N10 at 12–16 (ECF 173-11). The parties dispute the significance of those two conditions, as discussed below.

Petitioner and the government submitted medical literature and expert reports. The Special Master concluded that Petitioner had not established either (1) a logical sequence of cause and effect connecting her ovarian failure to her vaccine, or (2) that her ovarian failure was autoimmune in nature. Her reasoning was as follows.

In her *Althen* prong three analysis, the Special Master found that Petitioner's symptoms of ovarian failure began in May 2010. *See* Entitlement Decision at 40. Although Petitioner's contemporaneous medical records mention a menstrual period beginning on May 23, the Special Master interpreted Petitioner's December 7 fax as reporting three missed periods as of August 2010, *i.e.*, Petitioner's May, June, and July periods. *Id.* The fax, the Special Master wrote, provided "preponderant support

for [Petitioner's] menstrual irregularities and amenorrhea beginning in May of 2010." *Id.* The Special Master concluded on that basis that Petitioner's June 2010 vaccination could not have caused her ovarian failure. *Id.* The Special Master reasoned in the alternative that if Petitioner's hot flashes developed around August 1, 2010, her ovarian failure appeared too *late* to be consistent with an autoimmune response to the vaccination, which — depending on the study cited — typically appears within ten to 25 days. *Id.* at 41.

In her Althen prong two analysis, 4 Petitioner had argued that her positive tests for antinuclear antibodies predict autoimmune disease and that her psoriasis is an autoimmune condition comorbid with autoimmune ovarian failure. The Special Master appears to have assumed that Petitioner had both antinuclear antibodies and psoriasis. Id. at 34-35, 36-37. She found, rather — based on the medical literature and her evaluation of the parties' expert reports — that those conditions are not associated with premature ovarian failure. "[T]he medical literature," she wrote, "shows by a preponderance of evidence that a positive [antinuclear antibody] test does not, without more, predict autoimmune disease." Id. at 35. In addition, "while a positive [test for antinuclear antibodies] is known to be associated with some systemic autoimmune diseases, [ovarian failure] is not one of them." Id. That left Petitioner's antinuclear antibody results "irrelevant to a determination of an autoimmune etiology" for her ovarian failure. Id. at 36. Although the Special Master found that psoriasis is autoimmune in nature, id., she wrote that it had been "ruled out" as to Petitioner in 2013, was not diagnosed until much later in her history, and was not one of the autoimmune conditions associated with ovarian failure. *Id.* at 36–37.

DISCUSSION

Petitioner argues that the Special Master erred by finding (1) that Petitioner's ovarian failure predated her vaccine, and (2) that Petitioner failed to show that she has an autoimmune condition associated with ovarian failure. Pet. Br. at 1–2. This Court may set aside a special master's factual conclusions as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 42 U.S.C. § 300aa-12(e)(2)(B). When the special master's findings of fact are "supported by substantial evidence," they must be upheld. *Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citing *Whitecotton by Whitecotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1105 (Fed. Cir. 1996)). That standard is "well understood to be

⁴ Although characterizing Petitioner's ovarian failure overlaps with *Althen* prong one, the Federal Circuit has held that the question whether a given medical theory "accounted for" a Petitioner's particular injuries is a prong two question. *Hibbard*, 698 F.3d at 1364. No party takes issue with the Special Master's overall structuring of her analysis.

the most deferential possible." Munn v. Sec'y of Dep't of Health & Hum. Servs., 970 F.2d 863, 870 (Fed. Cir. 1992).

I begin with the Special Master's conclusion that Petitioner's ovarian failure developed in May 2010, before Petitioner's vaccination. That position is hard to understand or defend. On May 25, about a week before Petitioner received the Gardasil vaccine on June 4, her doctor wrote that Petitioner's most recent menstrual period had begun two days earlier. Pet. Exh. 2 at 65. The Special Master did not identify anything in the record of that visit suggesting that Petitioner's May period was late or otherwise unusual. Nor did she find that the medical records reporting Petitioner's May period were inaccurate or incomplete in any way. The Special Master was not bound to credit the medical records. See Kirby v. Sec'y of Health & Hum. Servs., 997 F.3d 1378, 1382–83 (Fed. Cir. 2021). But standing alone, the contemporaneous medical records — which "in general warrant consideration as trustworthy evidence," see Cucuras v. Sec'y of Dep't of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993) — do not seem to rationally support the Special Master's conclusion.

Instead, the Special Master relied on Petitioner's December 2010 fax saying that Petitioner "missed [her] menstrual cycle for about 3 months so [the doctor] took [her] off birth control[.]" Entitlement Decision at 40; see Pet. Exh. 3 at 32. According to the Special Master, Petitioner's fax described menstrual abnormalities beginning in May, counting three months back from Petitioner's August medical appointments. Entitlement Decision at 40. Yet the Special Master found that the fax was "consistent with" the notes for Petitioner's May doctor visit. Id. at 39.

That hardly makes rational sense either: If the fax does not contradict the May notes, then Petitioner must have had a period (without any abnormalities noted by the Special Master) in late May, just before receiving the Gardasil vaccine. Given that the Special Master did not find that the May medical record described any abnormalities in Petitioner's menstrual cycle, the only way to reconcile the May records with the December fax is to say that Petitioner's symptoms began *after* her May period.

The government argues that the handwritten phrase "discharge clear," appearing on Petitioner's May 25 medical record, indicates that her menstrual discharge was abnormal. See Resp. Br. at 17–18 & n.22; Tr. at 58. The phrase might be preceded, though, by a circle with a line drawn through it, which medical professionals sometimes use when they do not observe something. In fact, it seems that is exactly what the doctor intended: She marked Petitioner's breast exam as "normal" on the same medical record and handwrote the words "masses" and

"discharge" with the same symbol — meaning, presumably, that those abnormal breast conditions were not present. Pet. Exh. 2 at 65. The government also hypothesizes that if Petitioner had not missed her periods in May, June, and July, her doctors would not have ordered laboratory tests in August, Tr. at 60–62, though of course Petitioner was also experiencing hot flashes by then. Pet. Exh. 2 at 59. Regardless, the Special Master did not rely on those rationales to explain her decision, and the government cites no authority allowing this Court to affirm the Special Master based on speculative rationales developed here for the first time. Cf. Lemire v. Sec'y of Dep't of Health & Hum. Servs., 60 Fed. Cl. 75, 79 (2004) ("This post-hoc justification had nothing to do with the special master's explicit rationale.").

The Special Master's alternative reasoning — that Petitioner's symptoms appeared too late after the vaccine — is peculiar as well. The Special Master's thinking seems to have been that Petitioner's hot flashes began around the beginning of August. Entitlement Decision at 41. But the Special Master had also found that "secondary amenorrhea and cycle and frequency irregularities[] are the first symptoms or manifestation" of ovarian failure in patients like Petitioner. *Id.* at 38. Whenever Petitioner's hot flashes began, she told her doctor in December that she had missed at least some periods by August. Pet. Exh. 2 at 32. The Special Master consistently credited Petitioner's December account, and she found no evidence that Petitioner had a period in June or July. Entitlement Decision at 40. If the Special Master did not discount the December fax or find that Petitioner had periods in June or July, it is hard to understand how the Special Master could rationally have considered the hot flashes to be Petitioner's first symptom rather than the missed periods beginning in mid- to late-June — roughly in the time frame the Special Master noted for the normal onset of autoimmune ovarian failure. *Id.* at 41.

The Special Master also found no evidence that Petitioner's ovarian failure was autoimmune in origin. Petitioner argues that her ovarian failure was caused by autoimmunity because it developed when she had psoriasis, a supposedly comorbid autoimmune condition, and antinuclear antibodies. Pet. Br. at 6. Yet no reference to a psoriasis diagnosis appears in Petitioner's medical record until years later — in 2022 according to the Special Master, but at the earliest in a 2013 visit with a rheumatologist. Entitlement Decision at 36.

The Special Master's analysis of Petitioner's psoriasis diagnosis is questionable too. She found that Petitioner's medical literature does not associate psoriasis with ovarian failure, citing Petitioner's exhibits 126 and 127. Entitlement Decision at 36–37. But Petitioner claims that another one of the studies she presented to the Special Master could be read to do just that. See Pet. Exh. 128 (ECF 165-3); Tr. at 30–34; but see Tr. at 65–67 (government's contrary reading of the study). One of Petitioner's

experts described the study in those terms. See Pet. Exh. 124 at 4 (ECF 164-1) (Dr. David Axelrod, M.D.). The Special Master, at any rate, was "required to consider all relevant medical and scientific evidence of record ... even if it [was] not explained by the testimony of an expert." Moriarty by Moriarty v. Sec'y of Health & Hum. Servs., 844 F.3d 1322, 1330 (Fed. Cir. 2016). The Special Master's omission suggests that she did not perform a complete review of the entire record as the Federal Circuit requires.

The Special Master may also have erred in some of her conclusions about the onset of Petitioner's psoriasis. The Special Master wrote that the notes of Petitioner's 2013 rheumatology visit "ruled out" psoriasis. Entitlement Decision at 36. In fact, the doctor recorded that Petitioner had self-reported a possible eczema or psoriasis diagnosis from 2012, Pet. Exh. 6 at 1 (ECF 8-7), but that she did not observe any such condition herself, *id.* at 3, and recommended that Petitioner visit "dermatology for eval of psoriasis vs eczema," *id.* It makes little sense to say that a doctor who recommends a follow-up for a patient to check for or distinguish between two conditions has "ruled out" either condition. Entitlement Decision at 36. Whatever weight the medical record might deserve, the government does not defend the plain terms of the Special Master's reading. Tr. at 53–54.

In short, several of the Special Master's conclusions about Petitioner's symptoms and medical condition lack rational support in the record. Ordinarily, such errors might well call for remand.

But this Court and the Federal Circuit have ruled on a number of occasions that special master errors are not reversible unless the adverse party shows the error was prejudicial. See, e.g., Cedillo v. Sec'y of Health & Hum. Servs., 617 F.3d 1328, 1343 (Fed. Cir. 2010) (finding special master's error harmless when "it did not affect the outcome of the proceeding"); Hines on Behalf of Sevier v. Sec'y of Dep't of Health & Hum. Servs., 940 F.2d 1518, 1526–27 (Fed. Cir. 1991) (finding error harmless "because it did not change the outcome of the case"); see also A.Y. by J.Y. v. Sec'y of Health & Hum. Servs., 152 Fed. Cl. 588, 599 (2021); Johnson v. Sec'y of Health and Hum. Servs., 33 Fed. Cl. 712, 728–29 (1995); Cox v. Sec'y of Dept. of Health & Hum.

⁵ This Court presumes that a special master "considered the relevant record evidence even though he does not explicitly reference such evidence in his decision ... [except] where a special master indicates otherwise." *Moriarty*, 844 F.3d at 1328. Here, when the Special Master identified the evidence Petitioner meant to link psoriasis with ovarian failure, she left out the study that does so most directly. ⁶ The record might not be enough *by itself* to show that Petitioner had psoriasis in 2013, *see* Entitlement Decision at 36; Resp. Br. at 10, but all concerned seem to agree that Petitioner in fact was diagnosed with psoriasis eventually. The weight of record evidence is for the Special Master to determine, so long as her reading is not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B).

Servs., 30 Fed. Cl. 136, 142–45 (1993). Here, even if (1) Petitioner's condition postdated her vaccine, (2) psoriasis were comorbid with ovarian failure, and (3) the Special Master misinterpreted evidence about when psoriasis first appeared in Petitioner's record, Petitioner has not shown that it made any difference to the outcome.

Assuming both that Petitioner's ovarian failure postdated her vaccine and that psoriasis and ovarian failure are comorbid conditions, her theory still demands that the psoriasis and the ovarian failure existed closely enough in time to have something to do with each other. The Special Master found that Petitioner's psoriasis diagnosis in 2022 "does not have an appropriate temporal relationship to her [ovarian failure] symptom onset." Entitlement Decision at 37. At most Petitioner's medical record brings her psoriasis back in time to 2012 or 2013. Petitioner does not explain why that makes any practical difference, let alone develop an argument about what an "appropriate temporal relationship" might be, or show evidence that ovarian failure could be connected to psoriasis that only manifests two or three years after the fact.

Petitioner seeks to antedate her psoriasis by pointing to her positive tests for antinuclear antibodies. Put Petitioner tested negative for antinuclear antibodies in 2010, when her symptoms began. Pet. Exh. 2 at 41; see Entitlement Decision at 12. Petitioner points to no evidence that a positive antibody test in 2011 could show that psoriasis appearing in 2012 or 2013 was actually developing at the time of a negative antibody test in 2010. Petitioner has no explanation for the absence of such evidence, and the proposed link between her ovarian failure and her psoriasis breaks down without it.

Even if she had antinuclear antibodies around the time her ovarian failure developed — and no evidence suggests that she did — the Special Master also found that Petitioner had failed to prove that those antibodies are diagnostic of autoimmune disease generally or associated with autoimmune ovarian failure specifically. Entitlement Decision at 34–36. There is no causation without association, see Doles v. United States, 159 Fed. Cl. 241, 248 (2022), so the Special Master's conclusion means that the mere presence of antinuclear antibodies at a given time could not imply that Petitioner had psoriasis or that her ovarian failure resulted from autoimmunity. Petitioner points to no evidence that the Special Master's conclusion in that regard was arbitrary or capricious.

⁷ Petitioner might also frame the point in somewhat different terms: specifically, given that her ovarian failure began after her vaccine, when she had antinuclear antibodies, and that she was later diagnosed with an autoimmune condition, an inference of autoimmune ovarian failure makes the most sense. Tr. at 75. That phrasing ultimately does no more than obscure Petitioner's burden to prove causal connections between different pieces of her medical record.

The narrow reed of harmless error is enough to hold up the Special Master's decision. She appears to have erred as to the timing of Petitioner's ovarian failure. She also appears to have erred as to the timing of Petitioner's psoriasis and by overlooking evidence that the condition is associated with ovarian failure. But even assuming that Petitioner's ovarian failure developed soon after her Gardasil vaccine in 2010, and further assuming that Petitioner later showed signs of a comorbid autoimmune condition, Petitioner points to no evidence that her ovarian failure and autoimmune condition could have been associated with each other. Because the gaps in Petitioner's factual case are too wide to be bridged with lawyer argument alone, the Special Master's decision must stand.

CONCLUSION

For the foregoing reasons, Petitioner's motion for review is **DENIED**. The decision of the Special Master is **SUSTAINED**.

The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Stephen S. Schwartz STEPHEN S. SCHWARTZ Judge